K033994

MAR 2 5 2004

NOVABONE
SYNTHETIC BONE GRAFT PRODUCTS

510(k) Summary 12/18/03
NovaBone-BBG - Resorbable Bone Graft Substitute

1. Submitter Information:

Name:	NovaBone Products, LLC
Address:	13709 Progress Boulevard, #33 Alachua, FL 32615
Telephone:	(386) 462-7660
Facsimile:	(386) 418-1636
Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	NovaBone-BBG - Resorbable Bone Graft Substitute
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Classification Name:	Unknown

3. Legally Marketed Predicate Device:

Predicate #1:	PerioGlas – Synthetic Bone Graft Particulate [K992416, K962492, K930115] (Also named as NovaBone per K000149)
Predicate #2:	Biogran Bioactive Glass Synthetic Bone Graft Material [K952922]

4. Device Description

NovaBone-BBG is a synthetic resorbable osteoconductive bone graft substitute composed of two similar calcium phospho-silicate bioactive glass materials. The device is intended for dental intraosseous, oral, and cranio-/maxillofacial bony defects. The major component is a melt-derived calcium-phosphorus-sodium-silicate (Bioglass) designed specifically for its absorbability and osteoconductive nature. The second component is a calcium-phosphorus-silicate bioactive glass, chemically similar to the major component, but derived via a solution-gelation (sol-gel) process. The secondary sol-gel component is more rapidly absorbed from the graft site than the standard melt-derived component, opening additional space between the Bioglass particles for more rapid tissue infiltration and replacement by host bone during the healing process.

5. Intended Use

NovaBone-BBG - Resorbable Bone Graft Substitute is indicated to be packed into bony voids or gaps to fill and/or augment dental intraosseous, oral and cranio-

/ maxillo-facial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including: periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. NovaBone-BBG may be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either allograft or autograft bone or bone marrow as a bone graft extender. NovaBone-BBG is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

6. Technological Characteristics

The technological characteristics of NovaBone-BBG, PerioGlas, and Biogran are similar, although not identical. All are designed to be osteoconductive space-filling particulates to be gently packed into defect sites and to be used as a non-structural scaffold for the body's natural healing and bone regeneration process. To meet this design, the three devices are similar in nature, all being particulate, synthetic, inorganic, biocompatible and osteoconductive materials.

The main technological difference between NovaBone-BBG and the two predicate devices is that while the predicates are single-material Bioglass devices, the NovaBone-BBG contains Bioglass and a second sol-gel derived bioactive glass composition. The sol-gel glass is composed of calcium, phosphorus, and silicon, similar to the Bioglass component, but without the sodium. For all three devices, the materials are substantially absorbed within the six-month timeframe normally associated with bone remodeling, the devices being replaced by new bone tissue. The sol-gel phase of the NovaBone-BBG is more soluble than the standard melt-derived Bioglass, permitting a more rapid initial absorption and therefore providing more space for bone infiltration at an earlier period than for the predicates.

In vivo performance data comparing NovaBone-BBG and/or the individual sol-gel component to PerioGlas are summarized.

7. Warnings and Precautions

NovaBone-BBG does not possess sufficient mechanical strength to support load bearing defects prior to soft and hard tissue ingrowth. In cases where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

NovaBone-BBG is intended for use by clinician familiar with bone grafting and internal/external fixation techniques. NovaBone-BBG must not be used to gain screw purchase or to stabilize screw placement.

8. Complications

Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery. Complications specific to oral/dental use are those as may be typically observed for similar bone grafting procedures and may include: tooth sensitivity, gingival recession, flap sloughing, resorption or ankylosis of the treated root, abscess formation

9. Conclusion

NovaBone-BBG is claimed to be substantially equivalent to PerioGlas and Biogran as a non-structural osteoconductive bone void filler for oral and craniofacial defects. Side-by-side comparative *in vivo* performance data were presented. Additional supporting *in vitro* data were supplied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2004

Mr. David M. Gaisser
Director, Operations
NovaBone Products, LLC
13709 Progress Boulevard, #33
Alachua, Florida 32615

Re: K033994
Trade/Device Name: NovaBone –BBG- Resorbable Bone Graft Substitute
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: II
Product Code: LYC
Dated: December 18, 2003
Received: December 29, 2003

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

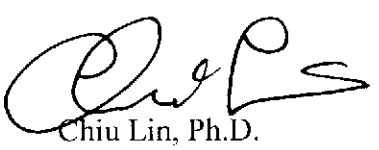
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K033994

Device Name: NovaBone-BBG - Resorbable Bone Graft Substitute

Indications For Use:

NovaBone-BBG – Resorbable Bone Graft Substitute is indicated to be packed into bony voids or gaps to fill and/or augment dental intraosseous, oral and cranio-/ maxillo-facial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including: periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. NovaBone-BBG may be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either allograft or autograft bone or bone marrow as a bone graft extender. NovaBone-BBG is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runge

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033994

Prescription Use X OR (Per 21 CFR 801.109) Over-The-Counter Use ___

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